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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/899,381	07/02/2001	Glenda C. Delenstarr	10010760-1	3033
7590 02/24/2005			EXAMINER	
Agilent Technologies, Inc. Legal Department, DL429			SISSON, BRADLEY L	
Intellectual Property Administration		ART UNIT	PAPER NUMBER	
PO Box 7599 Loveland, CO 80537-0599			1634	

Please find below and/or attached an Office communication concerning this application or proceeding.

## Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	Applicant(s)		
09/899,381	DELENSTARR ET AL.			
Examiner	Art Unit	_		
Bradley L. Sisson	1634			

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 15 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: The period for reply expires 3 months from the mailing date of the final rejection. The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). AMENDMENTS 3. A The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below): (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: See attached statement. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) \_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. X For purposes of appeal, the proposed amendment(s): a) X will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 13,15,16 and 18-23. Claim(s) withdrawn from consideration AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41,33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. 🔲 The request for reconsideration has been considered but does NOT place the application in condition for allowance because: 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). Other: <u>Statement attached</u>. Bradlev L. Sisson Primary Examiner

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#### New Matter

 The proposed amendment would raise a new issue, i.e., an issue of new matter. While attention has been directed to paragraph 80 of the specification as providing support for the new claim language, a review f the cited paragraph has fails to locate such support.

For convenience, claim 13, as proposed, is reproduced below.

- 13. (Currently Amended)

  A method of detecting the presence of an ensiyte nucleic acid in a sample, said method comprising:
  - (a) providing a nucleic acid array comprising:
    - at least one hybridization feature to which said analyte nucleic acid specifically binds under stringent hybridization conditions; and
    - at least one background feature, wherein said background feature is a
      polymeric composition that comprises background probes that do not
      specifically bind under stringent hybridization conditions to
      complementary buclete acids in any-target nucleic-acide of said
      sample;
  - contacting said nucleic acid array with said sample under stringent hybridization conditions;
  - (c) washing said nucleic acid array,
  - (d) detecting a hybridization signal from said hybridization feature and background signal from said background feature;
  - subtracting said background signal from said hybridization signal to obtain a background corrected hybridization signal; and
  - (f) relating said background corrected hybridization signal to the presence of said analyte target nucleic acid in said sample to detect the presence of said analyte target nucleic acid in said sample;

wherein said method is further characterized by including a target nucleic acid labeling step prior to said detecting step (d).

For purposes of examination, the claim, and more particularly the inserted language, has been interpreted as not allowing for any binding, no matter how minimal.

For convenience, paragraph 89 of the specification is reproduced below.

Examples of empirically observed inactive probes are shown in Table 1, infra. In particular, these probes have been observed to bind their complementary targets very minimally, yielding minimal signal levels in hybridization assays and as such are useful as background probes in the methods of the subject invention. The probes shown in Table 1 are from sequences originally designed to bind human G3PDH (SEQ ID NO: 1) and

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P53 (SEQ ID NO: 4) targets. When the probes were allowed to hybridize to their complementary specific targets, very poor binding was observed. Subsequently, other purified targets, as well as complex pool RNA, were also observed to bind very poorly to these probes. (Emphasis added.)

As can be seen above, the background probes/features do in fact bind to nucleic acids, albeit, "minimally." Such an aspect is not found in the cited paragraph. Accordingly, the introduction of language where it states that the background feature will not bind (to any degree) to a complementary sequence is not reasonably supported by the disclosure.

### Objection to the Specification

- 3. Argument is advanced at pages 4-5 of the response received 15 February 2005, hereinafter the response that the documents have been properly incorporated by reference, that the present case is distinguishable over that cited, and as such, the objection to the specification should be withdrawn.
- 4. The above argument ahs been fully considered and has not been found persuasive. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:
- 5. Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671,

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177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

As set forth In Ex parte Raible, 8 USPQ2d 1707, (BPAI, 1998)

The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree

We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In re de Seversky, 474 F.2d 671, 177 USPQ 144, (CCPA 1973).

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

### Rejection under 35 USC 103(a0

- Argument is advanced at pages 6-7 of the response that the method, as proposed in the amendment, is distinguishable over the prior art.
- The above argument as been fully considered and has not been found persuasive as the proposed amendment has not been entered. Accordingly, the rejection of claims under 35 USC 103(a) is maintained.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

10. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson Primary Examiner

B. L. Linor

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BLS 23 February 2005